

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/724,961	SCHENK, DALE B.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher Nichols, Ph.D.	1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 18 August 2003
2. ☒ The allowed claim(s) is/are 1,5,7-10,12,14,15,19-21,23,26,31,32,35,36 and 39.
3. ☒ The drawings filed on 10 October 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.
  - (b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the Examiner.
  - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.**

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)         |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 5 <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____    | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment                 |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance           |
|  | 9 <input type="checkbox"/> Other   |

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

1. The Amendment/Response filed 21 August 2003 has been received and entered in full. Claim 1 has been amended. Claims 2-4, 6, 13, and 16-18 have been cancelled. Claims 31-40 have been added. Claims remain withdrawn from consideration.
2. The Amendment/Response filed 10 October 2003 has been received and entered in full.
3. The Declaration under MPEP §2406.02 filed on 10 October 2003 has been entered.

### ***Withdrawn Objections And/Or Rejections***

4. All previous Rejections and Objections not made herein are withdrawn.

### ***Terminal Disclaimer***

5. The terminal disclaimer filed on 14 November 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Number 09/580018 has been reviewed and is accepted. The terminal disclaimer has been recorded.

## **EXAMINER'S AMENDMENT**

6. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

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In the Claims:

Claim 1 (Currently Amended) A method of prophylactically or therapeutically treating Alzheimer's disease, comprising administering to the patient an effective dosage of a pharmaceutical composition comprising an antibody that specifically binds to an epitope within residues 1-12 of A $\beta$  wherein the isotype of the antibody is human IgG1, ~~and thereby prophylactically or therapeutically treating the patient.~~

Claims 2-4 (Cancelled)

Claim 5 (Original) The method of claim 1, wherein the patient is human.

Claim 6 (Cancelled)

Claim 7 (Original) The method of claim 1, wherein the patient is asymptomatic.

Claim 8 (Original) The method of claim 1, wherein the patient is under 50.

Claim 9 (Original) The method of claim 1, wherein the patient has inherited risk factors indicating susceptibility to Alzheimer's disease.

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Claim 10 (Original) The method of claim 1, wherein the patient has no known risk factors for Alzheimer's disease.

Claim 11 (Cancelled)

Claim 12 (Original) The method of claim 1, wherein the antibody is a humanized antibody.

Claim 13 (Cancelled)

Claim 14 (Original) The method of claim 1, wherein the antibody is a polyclonal antibody.

Claim 15 (Original) The method of claim 1, wherein the antibody is a monoclonal antibody.

Claims 16-18 (Cancelled)

Claim 19 (Original) The method of claim 1, wherein the antibody comprises two pairs of light and heavy chains.

Claim 20 (Currently Amended) The method of claim 1, wherein the dosage of the antibody is 0.01 to 5 mg/kg body weight of the patient.

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Claim 21 (Previously Amended) The method of claim 1, wherein the antibody is administered with a carrier ~~as a pharmaceutical composition~~.

Claim 22 (Cancelled)

Claim 23 (Currently Amended) The method of claim 1, wherein the antibody is administered intraperitoneally, orally, subcutaneously, intranasally, intramuscularly, topically, or intravenously.

Claims 24-25 (Cancelled)

Claim 26 (Original) The method of claim 1, further comprising monitoring the patient for level of administered antibody in the blood of the patient.

Claims 27-30 (Cancelled)

Claim 31 (Original) The method of claim 1, wherein the antibody is a chimeric antibody.

Claim 32 (Currently Amended) The method of claim 1, wherein the patient has ~~the disease~~ Alzheimer's disease.

Claim 33 (Cancelled)

Claim 34 (Cancelled)

Claim 35 (Previously Added) The method of claim 1, wherein a single dosage of the antibody is administered on multiple occasions.

Claim 36 (Previously Added) The method of claim 35, wherein the single dosage is administered once every week, once per every two weeks, once a month, once every 3 to 6 months, or yearly.

Claim 37-38 (Cancelled)

Claim 39 (Original) The method of claim 1, wherein the method further comprises monitoring a response to the administration of the antibody in the patient.

Claim 40 (Cancelled)

7. Authorization for this examiner's amendment was given in a telephone interview with Rosemarie Celli (Reg. No. 42,397) on 14 November 2003.

In the Title:

PASSIVE IMMUNIZATION TREATMENT OF ALZHEIMER'S DISEASE

*Summary*

8. Claims 1, 5, 7-10, 12, 14, 15, 19-21, 23, 26, 31, 32, 35, 36, and 39 are hereby allowed.
9. The Examiner acknowledges that acceptance of the above Examiner's Amendment does not mitigate in any way, shape, or form, Applicant's right to pursue additional subject matter in continuation, continuation-in-part, and/or divisional applications pursuant to 35 U.S.C. §120 and §121.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
December 1, 2003

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**